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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,497	03/26/2004	Takashi Yamamoto	011350-334	7869

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EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	PAPER NUMBER
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,497	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 2, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapland (WO 99/04851). Shapland discloses a needle to deliver an agent into cardiac tissue comprising a sheath 134, an insertion member 142 disposed slidably in the sheath, an injection needle 148 having a bevel 168, and electrodes 160 at the distal end portion of the insertion member constructed so as to move into the target tissue (Page 13, lines 25-28; Page 7, lines 14-15). See Fig. 3.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 3, 5, 7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Tollner et al (US 2001/0031942) or Shapland in view of Chee in further view of Tollner. Claim 3 differs from the teaching of Chee in calling for the electrodes to be located not less that 1 mm from the leading edge of the insertion needle. Tollner discloses a percutaneous insertion catheter comprising sensing electrodes 6 located approximately 3 mm from the tip 4 of the catheter (Page 2, paragraph 30). This configuration eliminates the disadvantage of electrode

configurations that are hard to position by offering increased perceptivity lengthwise (Page 1, paragraph 14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place the electrodes of Chee in view of Iancea more than 1mm from the leading edge of the insertion member as taught by Tollner to increase perceptivity lengthwise.

5. Claims 4, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Chee et al (2002/018338). Claim 4 differs from Shapland in calling for a plurality of sets of electrodes. Claim 6 differs in calling for a pair of electrodes positioned at the distal end of the sheath. Chee teaches an apparatus for the treatment of the heart comprising a sheath with three sets of paired electrodes 136, 138, 140 disposed in the distal portion of the catheter so that the impedance of the tissue in the area surrounding the site of insertion of the needle can be measured (Page 8, paragraph 118). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Chee to include a plurality of electrodes and electrodes at the distal end of the sheath as taught by Chee so that the impedance of the tissue in the area surrounding the site of insertion of the needle can be measured.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Lederman (US 2003/0032936). Claim 10 differs from Shapland in calling for the distal end portion of the sheath to have a through hole communicating with the lumen. Lederman discloses a catheter 10 with a side through hole 16 in fluid communication with the lumen through which therapeutic or diagnostic agents may be delivered (Page 1, paragraph 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the sheath

disclosed by Shapland to include a side port as taught by Lederman to deliver therapeutic or diagnostic agents.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Lederman as applied to claim 10 above. Claim 11 differs from the teachings of Shapland in view of Lederman in calling for the through hole to be separated by not less than 1 mm from the end face of the distal end portion. At the time the invention was made, it would have been an obvious matter of design choice to place the through hole not less than 1 mm from the end face. Applicant has not disclosed that this distance serves any advantage or particular purpose of solves a stated problem. Furthermore, one of ordinary skill would expect the device of Shapland in view of Lederman to perform equally well with the through hole placed in any location. Therefore, it would have been prima facie obvious to modify the device of Shapland in view of Lederman as specified in claim 11 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Shapland in view of Lederman.

8. Claims 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Lum et al (US 6391005). These claims were previously indicated as allowable subject matter, however, an updated search revealed prior art that can be applied to these claims. Claim 13 differs from Shapland in calling for a puncture detecting device. Lum teaches an apparatus for sensing penetration depth comprising conductive ends for sensing the impedance of the tissue about the tip of the shaft as the tissue is being punctured so that the user can monitor when the

desired penetration has be achieved (Col. 3, lines 11-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shapland to include a puncture detecting device as taught by Lum so that the user can monitor when the desired penetration has be achieved.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee in view of Shapland. Chee discloses a method for treating the heart including inserting the catheter into the living body and advancing it to the neighborhood of the target tissue (Page 21, Claim 33). Chee further discloses the step of puncturing the target tissue based on measurements from the electrodes (Page 22, Claims 50 and 52). Chee further discloses the step of injecting therapeutic composition into the target tissue (Page 22, Claim 39).

10. Claim 15 differs from Chee in calling for at least one of the electrodes to be disposed at the distal end bevel of the injection needle. Shapland teaches a device having electrodes at the distal end bevel of the injection needle to monitor the impedance of the tissue being penetrated. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Chee to include the electrodes a the distal end bevel of the injection needle as taught by Shapland to monitor the impedance of the tissue being penetrated.

Response to Arguments

11. Applicant's arguments filed 1/20/2006 have been fully considered but they are not persuasive.

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that both the paired electrodes are disposed at the insertion member) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

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